



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GRAY DAVIS, GOVERNOR

**Licensing Committee Report**

**David Fong, Chair**  
**Clarence Hiura, Member**

**Report of March 4, 2003**

**FOR ACTION**

**RECOMMENDATION 1**

**That the Board of Pharmacy accept the criteria developed by the Licensing Committee as a guide when evaluating and approving accreditation agencies pursuant to Business and Professions Code section 4127.1(d).**

**Discussion**

Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

To meet the requirements of the new statute, the Licensing Committee requested that criteria be developed for which to evaluate the agencies. It was noted that board's approval should be based on the accreditation agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards. The following factors were developed for board consideration when evaluating an agency: periodic inspection, documented accreditation standards, evaluation of surveyor's qualifications, acceptance by major payors, unannounced inspections of sites, board access to accreditor's report on pharmacies, length of time in operation, out-of-state abilities to accredit, length of accreditation and process for reaccreditation. The criteria developed by the committee are in **Attachment A**.

**RECOMMENDATION 2**

**That the Board of Pharmacy consider the request from the Accreditation Commission on Healthcare (ACHC) that pharmacies accredited by ACHC are exempt from licensure pursuant to Business and Professions Code section 4127.1(d).**

## **Discussion**

ACHC has requested approval as an accreditation agency as authorized under current law. ACHC currently accredits both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. ACHC revisits each accredited entity every three years. Currently, 11 California pharmacies are accredited by ACHC.

Stuart Venook representing ACHC provided an overview of the accreditation process. He stated that the company reviews the pharmacy's policies and procedures in advance of the site visit, they observe nurses at the home, review patient records, and they validate the pharmacy's processes through a site visit and review of the complaint log. ACHC is located in North Carolina and was formed as an alternative to JCAHO, which primarily accredits hospitals. He stated that they have over 400 clients in 43 states.

The committee requested that ACHC submit additional information to be provided as part of the evaluation process. They requested the names of the 11 California pharmacies that are currently accredited, the number of pharmacies that have been denied accreditation or issued a "provisional" accreditation (and specifically any in California), the length of the accreditation process and the process for reaccreditation. ACHC's response is in **Attachment B**.

## **No Action**

### **Implementation of the Licensure and Inspection Program for Pharmacies that Compound Injectable Sterile Drug Products**

Effective July 1, 2003, a pharmacy may not compound sterile injectable drug products in California unless:

- The pharmacy is specially licensed by the board as a sterile compounding pharmacy, or;
- The pharmacy has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board (there is a pending request from ACHC)

All pharmacies that compound sterile injectable drug products must follow the board's regulations for sterile compounding (CCR 1751).

Recently promoted Supervising Inspector Dennis Ming is responsible for the implementation of this new program. The application forms are on the board's website and to date the board has received one application. To assist pharmacies with compliance, Mr. Ming developed a self-assessment form that will be available on the board's website. The initial licensure inspection will be by appointment and all inspectors will be trained on the inspection process. Training is set for the first week in May.

## **Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation**

At the January meeting, the board created the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBMs) Regulation. This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. The first meeting was held March 4, 2003, with Licensing Committee Chair Dave Fong facilitating the meeting. The meeting was well attended and the meeting summary is attached. **(Attachment C)** The next ad hoc meeting is scheduled for June 4<sup>th</sup>, in the morning, before the Licensing Committee meeting.

### **Meeting Summary of March 4, 2003 (Attachment D)**

### **Application/Licensing Statistics (Attachment E)**

### **Competency Committee Report (Attachment F)**

The next pharmacist licensure examination is scheduled for June 17<sup>th</sup> and 18<sup>th</sup>, at the San Jose Convention center.

### **Proposed Strategic Objectives for 2003/04 (Attachment G)**

While the proposed strategic objectives will be formally adopted during the board's strategic planning session, please review them for priority and clarity.

### **Status Report on Committee Goals for 2002/03 (Attachment H)**

# *Attachment A*

# Memorandum

To: Board Members

Date: April 14, 2003

From: Paul Riches  
Legislative Analyst

Subject: Approval of Accrediting Entities

## Background on Senate Bill 293

Senate Bill 293 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement established by Senate Bill 293 (Section 4127.1 (d) of the Business and Professions Code). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The Accreditation Commission for Health Care (ACHC) has requested the board to approve it as an accrediting entity under Senate Bill 293. ACHC currently accredits both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. A copy of material describing ACHC and a copy of its accreditation manual is attached for your reference. ACHC revisits each accredited entity every three years and anticipates implementing random interim surveys of its accredited entities. Currently, 11 California pharmacies are accredited by ACHC.

The Licensing Committee developed the following criteria for the evaluation of applications by accrediting entities for board approval. The following criteria are the result of the Licensing Committee's discussions, including a presentation to the Committee by an ACHC surveyor. ACHC followed up on specific questions raised by the Committee and those responses are follow this memo.

## Factors to Consider

The evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards. The following factors should be considered when making such an evaluation:

- 1. Periodic inspection** – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.

2. **Documented accreditation standards** – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payors** – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

# *Attachment B*

## ACHC and Proposed Factors for Approving Accrediting Agencies

Factor	ACHC
Periodic inspection	Requires inspection upon initial application and every three years for re-accreditation.
Documented accreditation standards	Has documented accreditation standards and applicable scoring guidelines for surveyors.
Evaluation of surveyor's qualifications	<p>According to ACHC surveyors must have the following minimum qualifications.</p> <ol style="list-style-type: none"> <li>1. Currently Registered Pharmacist with a BS in pharmacy, a PharmD is preferred.</li> <li>2. Five years recent home care or community based experience, infusion experience, or specialty pharmacy experience, at least two of which, were in administration, management, or supervision and having experience in planning, implementation and evaluation of quality improvement through a licensure or accrediting survey.</li> </ol>
Acceptance by major California payors	Blue Cross, CCN, and Blue Shield
BOP Inspection of California accredited sites	
Board access to accreditor's report on individual pharmacies.	A copy of the surveyor's report is kept in each accredited pharmacy.
Length of time the accrediting agency has been operating.	ACHC has been operating nationally since 1996.
Ability to accredit out-of-state pharmacies.	ACHC operates in other states.



ACHC Presentation  
To the  
California Board of Pharmacy

1. What constitutes a denial of accreditation? Any scope of service section that is below 70% or the overall score of the survey is below 70% will result in denial of accreditation to the applicant organization. The organization has two options.
  - (1). Prepare for a new survey. The company can reapply no sooner than six months from the date of denial. The applicant organization must undergo an entirely new survey. Recommendations for correcting deficiencies are provided to the company.
  - (2). Appeal the decision. If the company denied believes that the survey score was in error, it may submit a written appeal within 30 days of the decision date. The ACHC Board Chair will appoint a five-person panel with Commissioners who were not involved with the initial review to hear and consider the appeal. The applicant organization will be required to make a presentation to the panel.
2. What constitutes a deferral of accreditation? If the survey score is in the range from 70-84, the company is deferred any decision of accreditation. The Summary of Findings will outline deficiencies and make recommendations. The Review Committee will require a Plan of Correction to be submitted within 30 days of the decision. The committee will give the company up to six months to make corrections and provide evidence of compliance. If the deficiencies are policy related, evidence of changes can be mailed to the committee. If the deficiencies involve patient care, a return focused visit by the surveyor will be required.
3. Have any organizations been denied by JCAHO, but accredited by ACHC? None that we are aware of.
4. What payers recognize ACHC? ACHC accreditation is recognized by most national and state third party payers including, but not limited to, AetnaUS Healthcare, Humana, CCN Managed Care, Cigna Healthcare, Anthem Health Plans, most Blue Cross Blue Shield and United Healthcare state plans. In California, Blue Cross, CCN, and Blue Shield. Pacific Care of OR, WA and AZ reviewed ACHC standards and approved them last year. Standards have been sent to Pacific Care of CA and Healthnet. We are still waiting to hear from them.
5. What companies are accredited by ACHC in California?
  - (1). Nutrishare, Elk Grove
  - (2). Hoffman Home Care, Bakersfield
  - (3). Coram Healthcare, Santa Barbara
  - (4). Coram Healthcare, Tustin
  - (5). Coram Healthcare, Ontario
  - (6). Coram Healthcare, Glendale
  - (7). Coram Healthcare, San Diego
  - (8). LivHOME, Los Angeles
  - (9). LivHOME, Newport Beach
  - (10)LivHOME, Santa Barbara
  - (11)LivHome, Los Angeles

Current Applications for companies in California:

Mini Med Distribution Corporation, Northridge  
Proactive Healthcare Systems, Van Nuys

HOME HEALTH \* HME \* HOME INFUSION \* AIDE \* HOSPICE \*  
SPECIALTY PHARMACY \* WOMEN'S HEALTHCARE FITTER SERVICES \*  
MAIL ORDER MEDICAL SUPPLIES \* RESPIRATORY NEBULIZER MEDICATION \* REHABILITATION  
TECHNOLOGY SUPPLIER SERVICES

# Setting Standards in Accreditation



Welcome to ACHC, Inc. a national organization established and developed by home care and community-based providers. The Commissioners, Advisors, and Staff are committed to providing the industry an accreditation program that influences companies to maintain sound ethical business operations and to remain focused on delivering quality care and services to consumers

**Accreditation Commission for Health Care, Inc.**  
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**E-mail [achc@achc.org](mailto:achc@achc.org)/ [www.achc.org](http://www.achc.org)**

# About ACHC, Inc.

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## Mission, History and Philosophy

The Accreditation Commission for Health Care, Inc. (ACHC) is an independent, private, not-for-profit corporation established in 1986. The program was created in response to provider concerns for quality in-home aide services and the desire for an alternative program.

ACHC offers an accreditation program developed by providers for providers with emphasis on user-friendly standards and interpretations and friendly, helpful staff and surveyors. ACHC accredits Medicare certified home health agencies, home infusion companies, specialty pharmacy companies, home care aide programs, home medical equipment suppliers, hospices, companies that specialize in services and products for post breast surgery patients, mail order medical suppliers, respiratory nebulizer medication programs, and rehabilitation technology supplier services companies.

ACHC has gained respect and recognition as an accrediting body that ensures a "voice" for providers. It has adopted a participatory approach to standards development that has resulted in criteria that are relevant, reasonable and user-friendly in language. ACHC emphasizes the philosophy that the accreditation process should be a helpful, positive experience for the provider.

We expect considerable growth in the home care industry for many more years. The current attitude among many home care professionals shows a strong interest for competition with accreditation. Due to this interest, ACHC began offering its services nationwide in 1996 and now has accredited locations states from coast to coast. Patients served by ACHC accredited companies are in all states and Puerto Rico.

The following is ACHC's Core Mission, Purpose, and Values:

CORE PURPOSE: To help our customers succeed.

CORE MISSION: To support healthcare organizations and providers in optimizing wellness through standards that promote the effective, efficient delivery of quality services and products.

CORE VALUES:

- Integrity
- Relevance
- Innovation
- Enhancing Outcomes
- Excellence in all Things
- Flexibility Without Compromising Quality
- Concern for the Entire Healthcare Continuum



# Accreditation Programs

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The Accreditation Commission for Health Care, Inc. is pleased to offer accreditation programs tailored specifically to the home care industry. The accreditation standards are the result of the combined effort of ACHC staff and volunteer industry leaders who gave their time to help in the development of standards and criteria. We have made our standards understandable with realistic expectations of daily operations.

## Home Health

Home health care replicates the hospital situation in the home for non-critical patients and gives the primary care givers and/or family an opportunity to participate in the care planning process. The integrated continuum of care covers the patient from physician to hospital to home and alternate site facilities. Home Health accreditation includes Medicare certified and non-certified services provided to a patient in a home setting to help his or her recovery from acute or other care and/or increase independence, improve quality of life and decrease overall health care costs while improving care.

## Home Infusion

The infusion therapy continuum of care includes IV drug mixture preparation, IV administration, therapy monitoring, patient counseling, in-service education and quality assurance as provided upon receipt of the physician's order, coordinated by the care manager or discharge planner, prepared by the licensed pharmacist and administered by the home health care nurse.

## Specialty Pharmacy

A specialty pharmacy company is one that dispenses biotechnology medications, usually self-injectable, to a patient's home, physicians' office, or clinics specializing in certain chronic disease states. Examples of specialty pharmacy drugs include growth factors, Avonex, Rebetrone, Remicade, and Viracept Epiriv.

## Home Medical Equipment

HME includes durable medical equipment, home health care products, medical supplies and/or respiratory therapy services provided to a patient in a home or alternate site setting to help recovery from acute or other care and/or increase independence, improve quality of life and decrease overall health care costs while improving care. The standards include rehabilitation technology supplier services.

## Hospice

Hospice is the care of terminally ill patients in the health care setting that emphasizes quality of life through patient and family involvement in the home and pain management. All health care efforts are directed toward the patient and family as the unit of care including nursing, social work, personal care, bereavement, spiritual and other related services.

## Aide

Aide service (*i.e. home care aide*) encompasses all levels including Personal Care Services, chore, companion sitters, and homemakers.

## **Women's Healthcare Products and Services**

Women's health encompasses the physical and psycho social needs for women's personal care products and services such as post-mastectomy, including prosthesis fitting, compression therapy and hair loss, as well as pregnancy, child birth and incontinence. ACHC accredits fitter services.

## **Respiratory Nebulizer Medication Pharmacy Program**

A Respiratory Nebulizer Medication Pharmacy program is one that dispenses aerosolized single patient dose respiratory medications. The medications may be prepackaged or compounded by the pharmacy. These medications are usually delivered directly to the client's home by use of outside delivery services such as UPS, FedEx or US Mail, but may also be delivered by the organization itself. These medications usually benefit a targeted patient population with a chronic disease such as Emphysema, Chronic Bronchitis or Asthma. Examples of Respiratory Medications include Beta Adrenergic Bronchodilators, Anticholinergic Bronchodilators, Corticosteroids (Anti-inflammatory Agents), Cromolyn Sodium, Mucolytics, and Antibiotics.

## **Mail Order Medical Supply Services**

The storage and delivery of home medical equipment and/or medical supplies designed to meet the needs of a client requiring the product for their medical management in the home care setting. These services are generally prescribed by a physician and may be reimbursable through a third party payer or contract. These items are sold to the client and are usually disposable or semi durable in nature. The supplier does not provide in-home care. Any equipment provided must not require ongoing maintenance by the provider.

## **Rehabilitation Technology Supplier Services**

Rehabilitation Technology services are defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental control, augmented communication and other equipment and services that assist the person in performing their activities of daily living. Rehabilitation technology services facilitate and/or enhance access and independence thereby improving the person's quality of life.



# Steps Toward the Accreditation Process

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## Accreditation Manual Request

When requested, ACHC staff will assess the prospective applicant's Manual needs. Orders for Manuals may be placed via telephone, fax, e-mail or mail. Advance payments are required prior to shipment, and may be made with check, cash, money order, or credit card.

## Determine if your Organization meets the Eligibility Criteria.

- The applicant has been actively providing in-home/or alternate site services for no less than four months and has served a minimum of four (4) clients before submitting an application.
- The applicant must submit ACHC 's entire application package
- The applicant agrees to grant ACHC and/or its designated agents full access to all records (including client and personnel) that are necessary to ascertain compliance with the standards.
- The applicant agrees to pay fees according to the Accreditation Price List.
- The applicant agrees to submit application for all branch offices. (Please contact ACHC to determine qualifying locations.)
- The applicant must be operating within the United States and/or its territories.

## Self Assessment/Focus Study

The organization utilizes all ACHC standards to do a self-assessment to determine level of compliance and makes necessary changes to assure substantial compliance with policies, internal processes, and quality of services performed.

Accreditation Manuals contain the same core standards. The language in each manual is focused on the particular environment in which the provider operates. Therefore, the wording of interpretations will differ according to the manual.

# Preparing for the Survey

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Preparation time will vary with each organization depending upon its resources and ability to stay focused on a systematic plan of evaluating compliance with ACHC standards and making the necessary changes in policy and practice to bring the company into compliance.

It is suggested that the applicant provider utilize a team approach. For internal use only, ACHC standards may be reproduced and distributed among the team members. Staff should read thoroughly the sections that contain Accreditation Policies and Procedures; the Interpretive Guide to Standards; Instructions for Organizing Evidence; and the Preliminary Evidence Report.

Develop an action plan that staff can follow for conducting a self-assessment and for correcting areas that need to be implemented or improved. Make sure that all staff participants in this process understand the need for the company to be in compliance with policy, process and performance. Policies should reflect actual process of how you operate and function within your business and how delivery of services are carried out. Performance will measure how well you provide services to clients.

It is also suggested that the team meet on a regularly scheduled basis to determine progress and to exchange ideas. This stage will take time, but is designed to help the company identify strengths and weakness so that appropriate corrective actions can be made. These meetings can also be used to plan periodic audits on different topics so that you can realistically assess your progress. This will illustrate specific areas that may need more attention prior to the survey visit.

During your preparation, you may also want to talk with associates that have already experienced the accreditation process. Many good tips can be learned and help rendered through networking. The format and use of language in the Accreditation Manual has been designed in a way that is easy to understand. If you have any questions about a standard, please contact our office.

Near the end of the preparation process, meet with all of your staff to discuss the survey visit process and answer questions. The better you coach your staff the better they will respond during the survey visit. It is normal to have some anxiety. However, assure your staff that ACHC surveyors will have a positive attitude and will be at your organization to measure compliance with ACHC standards and will be helpful.

Completion of survey preparation means that you are able to demonstrate that your organization fulfills its mission, practices what its policies read and is in substantial compliance with ACHC standards. At this point it is time to submit the Preliminary Evidence Report and schedule the on-site visit.

# Beginning the Accreditation Process

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## Application for Accreditation

Applications for accreditation are accepted at anytime. The application for accreditation forms are located inside the Accreditation Manual; section 4 and consist of the Application for Accreditation, Attachment I- Branch Office Information, Statistical Data Form and Letter of Understanding. These forms must be signed by the designated organization representative.

## Preliminary Evidence Report

The Preliminary Evidence Report is submitted with the application. The policies submitted will be forwarded to the assigned surveyor(s) to conduct a Desk Review. The policies will be reviewed approximately two to three weeks prior to the survey visit.

The surveyor(s) may contact the applicant organization if anything is missing. The applicant organization may submit additional supporting evidence prior to the survey visit or label and make available at the time of the visit.

## Fees

The accreditation fee is based upon the organization's defined program services and statistical information of the last completed fiscal year prior to accreditation. Check with the ACHC office to verify fees due.

## Application Review and Number Assignment

Once the application has been reviewed for completion, ACHC staff will assign a survey number to the applicant.

## Conflict of Interest/Surveyor Assignment

The applicant organization and the prospective surveyor will be contacted prior to the final surveyor assignment to determine any possible conflict of interest. The applicant organization will be provided the name, current employer(s) and other pertinent background information concerning the prospective surveyor. The organization is asked to document any "conflict of interest" on the provided form with the date and signature of the designated applicant official. If a documented conflict of interest is returned from the applicant organization, another surveyor will be assigned. ACHC will make arrangements for a mutually agreeable time for the site visit.



# The On-Site Survey

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The surveyor(s) will conduct a review of the following: personnel files; client records, budgetary information; policies and procedures, the quality improvement plan and operational and service delivery outcomes. Interviews will be done with staff and clients.

## *Typical Agenda for the Site-Visit*

### On the First Day

Opening Conference

Interview the leader/executives of the organization and representative of the Board and/or Advisory Committee

Interview the quality improvement coordinator

Interview the program/clinical supervisor

Review contracts and interview business manager/accounting clerk

Select and review personnel records

Select and review client records

Select clients to be interviewed

Develop agenda for visits and interviews

(For some small organizations the survey may be one day)

### On the Second Day

Visit and interview clients (some interviews may be done by telephone)

Interview staff members

Interview case managers (when applicable)

Interview service supervisors

Interview an intake worker who describes services to the public

Review documented outcomes of quality improvement activities

Review minutes of staff meetings, Board meetings and planning sessions

Exit Conference

### Additional Days may be added as necessary

Depending upon the number of programs, services offered, size of the organization, number of branch locations, similar activities may be conducted for several days by a surveyor or team of surveyors.

# Scoring and Reporting the Findings

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## Scoring

Once data is collected, the sum of actual points divided by the total possible points related to each standard results in a compliance percentage threshold which is averaged for each section. Standards related to supervision of services and contracts must be in compliance for accreditation. The organization must score a minimum threshold of 85% for each resource manual section and for each service provided.

## Reporting Findings

Completed Data Collection and Scoring Tools are forwarded to ACHC Accreditation Services, along with documented surveyor comments. The Scoring Summary is completed by ACHC staff utilizing the Data Collection / Scoring Tools and comments made by the surveyor. This is forwarded to the Accreditation Review Committee for consideration.

## Review Committee

The Accreditation Review Committee represents the third level of peer review prior to the committee's decision. The committee activities include a review of the overall survey-documented evidence, the scoring summary and an evaluation of the surveyor recommendations. Review Committee comments will be documented on the Summary of Findings Report. Review Committee decisions are reported to the Board of Commissioners at least quarterly. The Review Committee will approve, defer or deny accreditation.

## Decision Notification

The office sites and services for which accreditation has been granted are described in a letter of accreditation approval included with the Certificate of Accreditation. Additional copies of the certificate are provided (at no additional charge) for all branch locations included in the survey process when an organization has multiple sites.

Accreditation is awarded for a period of three years from the first of the month following the date a decision is rendered (anniversary date). Accreditation is contingent upon receipt of total fees and continuing compliance with the Standards and Accreditation Policies and Procedures.

ACHC reserves the right to make announced or unannounced on-site visits at any time during a three (3) year accreditation cycle to determine continuing compliance with standards. If an interim visit results in the need for a full survey, the organization will be responsible for appropriate fees.

Organizations must accurately describe only the program(s) and services accredited by ACHC when advertising its accreditation status to the general public. False or misleading advertising shall be grounds for withdrawal of accreditation.

# *Attachment C*



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STATE AND CONSUMER SERVICES AGENCY  
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GRAY DAVIS, GOVERNOR

## **LICENSING COMMITTEE**

### **AD-HOC Committee on Pharmaceutical Benefit Managers (PBMs) Regulation**

#### **Meeting Summary**

**DATE:** March 4, 2003

**TIME:** 1:00 p.m. – 4:10 a.m.

**LOCATION:** 400 Street, 1<sup>st</sup> Floor Hearing Room  
Sacramento CA 95814

**Ad Hoc Committee Members:** Bill Powers, Public Member  
Caleb Zia, Public Member  
Andrea Zinder, Public Member

**Licensing Committee Members:** Dave Fong, Pharm.D.  
Clarence Hiura, Pharm.D.

**Staff Present:** Patricia Harris, Executive Officer  
Ronald Diedrich, Deputy Attorney General

**Commenters:** Mary Ryan, Medco Health Solutions  
Debra Stern, Academy of Managed Care Pharmacy  
Kristine Lee, American Healthcare  
John Cronin, Pharmacy Owner  
Regina Benjamin, National Community Pharmacists Association  
William Hermelin, Academy of Managed Care Pharmacy  
Steve Gray, Kaiser Permanente

#### **Introductions**

Licensing Committee Chair Dave Fong explained that at its last meeting, the Board of Pharmacy created the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBMs). This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. As Chair of the Licensing Committee, Dr. Fong stated that his role is that of facilitator. He acknowledged that the purpose of this first meeting is to explore what PBMs do in the context of the board's public protection mandate and necessity for regulation.

**The following is a summary of the comments. It does not represent actual findings of the Ad Hoc Committee, the Board of Pharmacy or is it all-inclusive.**

## **General Information**

- ❑ Employers are the largest payers of prescription drug benefits in California
- ❑ PBMs are companies that administer pharmaceutical benefits for health plans, HMOs, and employers
- ❑ There are approximately 300 PBMs nationally that cover 60-65% of lives for private payors and 10% of the lives for the public sector
- ❑ Pharmacy benefits are considered “riders” on the insurance plans – the pharmacy benefits are typically separate from the medical benefits

## **PBMs functions**

- ❑ Claims processing
- ❑ Own and operate mail order pharmacies that are licensed pharmacies
- ❑ Establish the pharmacy network
- ❑ Design the Pharmacy Benefit on behalf of the client employer, health plan, etc.
- ❑ Negotiate rebates with the drug manufacturer
- ❑ Determine reimbursement rates to pharmacies and other healthcare providers in the network
- ❑ Perform formulary management
- ❑ Perform drug interaction screening
- ❑ Initiate therapeutic substitution with prescribers for formulary compliance
- ❑ Perform drug utilization review
- ❑ Disease state management

## **PBMs functions that are considered the practice of pharmacy and should be regulated (performed by pharmacists)**

- ❑ Formulary management
- ❑ Drug interaction screening
- ❑ Initiate therapeutic substitution with prescriber’s consent (drug “switching” for formulary compliance)
- ❑ Drug utilization review
- ❑ Disease state management

## **Formulary Design and Management**

- ❑ A formulary is a therapeutic list of prescription drugs chosen by a PBM pharmacy and a Pharmacy and Therapeutics committee on the basis of safety, efficacy and cost
- ❑ As it relates to health plans, state approval is required for the drug benefit design and any significant changes to the plan design or administration of the program
- ❑ Health plans must offer an appeal process for non-covered drugs based on medical necessity including a neutral third party review
- ❑ Health plan patients must be given the ability to continue on an existing drug therapy even if there is a formulary change (continuity of care) – an exception to this rule is when a benefit exclusion is approved by the health plan regulator during annual benefit changes
- ❑ Closed Formularies – drugs not listed in the formulary are not covered, although some health plans permit physicians to follow a prior authorization process to obtain approval for a patient to receive coverage for an unlisted drug

- ❑ Three-Tier Plan – patients have broad access to and choice of prescription drugs, but pay different co-payments (i.e. the lowest co-pay is for generic drugs; the next highest co-pay is for formulary or preferred drugs; the highest co-pay is for “non-preferred” and non-formulary drugs).
- ❑ Pharmacy and Therapeutics (P&T) Committee – health providers representing various medical and pharmacy specialties, and academia usually develop the formularies of preferred and nonpreferred drugs
- ❑ Drug selection process should focus on cost-effective quality of care
- ❑ Rebates and prescription drug costs should not be the driving force of formulary design – rebates provide a financial incentive for PBMs to include certain products in their formulary lists and to educate physicians and patients about these products. A majority of these rebates or financial incentives should be passed back to the client or health plan to lower overall prescription costs
- ❑ PBMs may design plans that may require patients to be switched to another drug in a therapeutic class for a better cost-effective outcome
- ❑ PBMs often negotiate rebates and/or discounts from the drug manufacturer for the drugs used by the members exercising their pharmacy benefit
- ❑ Some PBMs contract for fees with the drug manufacturers for a variety of services

### **Drug Utilization Review**

By using data captured in the adjudication of provider claims, PBMs can:

- ❑ Target inappropriate prescribing
- ❑ Identify drug therapy issues with patients
- ❑ Stop prescriptions at point of sale when there may be drug-drug interactions

### **Provider Issues**

- ❑ Reimbursement is not adequate to cover costs of compliance with California pharmacy law required to operate a pharmacy, provide pharmacists’ care and dispense prescriptions
- ❑ Consumers do not know their pharmacy benefits and the responsibility to communicate coverage to the patient falls to the pharmacist (e.g. why isn’t the drug covered?)
- ❑ Fee powerless against the PBM – the PBM controls the reimbursement
- ❑ Providers have no recourse when they have been wronged by a PBM
- ❑ Contracts offered to providers are perceived as a “take it or leave it” basis – no opportunity to negotiate – reimbursement is not based on any actuarial data
- ❑ No connection between the PBM and the consumer
- ❑ No disclosure of the rebates and/or fee from the drug manufacturer and the PBM
- ❑ Lack of timely payments from the PBM

### **“Noise” in the System - Electronic Communications**

- ❑ Too many eligibility, drug coverage and DUR messages sent back to the pharmacy leading to workflow and patient service issues
- ❑ Consumers don’t know what prescription drugs are covered and pharmacists must intervene
- ❑ Prescription drugs are prescribed that are not on the formulary and the pharmacist must contact the prescriber, which delays the medication to the patient

- ❑ Pharmacies deal with a multiple PBMs
- ❑ 75% of pharmacists time is spent addressing third-party payer issues – impedes pharmacists' care
- ❑ No consistency among the many formularies which creates confusion for the physicians, pharmacies, and patients

### **PBM Oversight**

- ❑ Responsibility of Employer/Health Plan
- ❑ Employer/Health Plan will typically hire a consultant for guidance with the design of the pharmacy benefit, selection and oversight of the PBM
- ❑ PBM is usually selected through the Request for Proposal (RFP) process
- ❑ Employer/Health Plan audits PBM for compliance with terms of contract
- ❑ Rebates/drug costs should be disclosed to the Employer/Health Plan to determine actuarial for costing out drug benefits and premiums

### **Current Regulation**

- ❑ Health maintenance organizations (HMOs) and point of service plans (PSOs) that offer prepaid health benefit package are regulated by the Department of Managed Care
- ❑ Preferred provider organizations (PPOs) which offer a discounted fee-for-serve insurance and traditional indemnity insurers are regulated by the Insurance Commissioner
- ❑ Company sponsored insurance plans are regulated by the United States Department of Labor and are exempt from state regulation
- ❑ Under California law, a health plan bears the responsibility to assure that enrollees are provided with medically necessary services in compliance with the law whether the health plan provides those services directly or indirectly through contracts with intermediaries
- ❑ For health plans, state approval is required for the drug benefit design and any significant changes to the plan design or administration of the program

### **What activities of the PBMs should be regulated for public protection and quality of care? (Suggested proposals)**

- ❑ Formulary development and drug coverage – requirements for P & T Committees – criteria for drug selection
- ❑ Therapeutic substitution – for formulary compliance, best interest of the patient, or increased profits for the PBM
- ❑ Rebates – public disclosure of rebates/drug prices/reimbursement rates
- ❑ Pharmacist authority for therapeutic substitution of formulary drugs
- ❑ Clarification of PBM functions that must be performed by a pharmacist
- ❑ Recourse for providers with disputes against PBMs

### **Draft PBM Model Legislation - National Community Pharmacists Association (NCPA)**

- ❑ Places the primary responsibility for regulation with the state insurance department
- ❑ Requires the Board of Pharmacy to review the PBM's plan of operation to ensure it is consistent with the Pharmacy Act

- ❑ Reviews the audit process when there is an unresolved dispute between the PBM and the pharmacist/pharmacy – audit function allows the Board of Pharmacy to review the operation of the PBM as it relates to the plan of operation filed with the board

#### **National Association of Boards of Pharmacy (NABP) – Task Force on Licensing of PBMs**

- ❑ Defined PBMs
- ❑ Identified PBM activities that encompass the practice of pharmacy: disease state management, disease compliance management, drug adherence management, drug interaction management, drug utilization management, formulary management intervention, generic alternative program management, generic incentive program management, medical and/or drug data analysis, patient DUR services, prior authorization services, provider profiling and outcomes assessment, refill reminder program management, therapy guidelines management, stop therapy protocol management; wellness management and maintenance of confidential patient information

#### **Other States**

- ❑ New legislation in Georgia requires the licensure of PBMs by the Board of Pharmacy
- ❑ Legislation has been introduced in the following states: Arkansas, Colorado, Illinois, New Mexico and Wyoming. The legislation is based on the NCPA PBM Licensure Model.
- ❑ Legislation has been introduced in other states that would require the licensure of PBMs but not necessarily using the NCPA model. These states are: Hawaii, Oregon, Vermont, Maine, New Jersey, Tennessee, Kansas, and Maryland.

#### **Closing Comments**

Licensing Committee Chair Dave Fong stated that the Ad Hoc Committee will provide a summary of this meeting to the Board of Pharmacy at its meeting in April. At which time, the committee will determine its next steps. Future meetings will be scheduled on the same days as the Licensing Committee meetings. The next meeting is scheduled for June 4<sup>th</sup>, from 9- 12 noon. Dr. Fong adjourned the meeting at 4:10 p.m.



# *Attachment D*



**California State Board of Pharmacy**

400 R Street, Suite 4070, Sacramento, CA 95814-6237  
Phone (916) 445-5014  
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GRAY DAVIS, GOVERNOR

**LICENSING COMMITTEE  
Meeting Summary**

**DATE:** March 4, 2003

**TIME:** 9:00 a.m. – 11:30 a.m.

**LOCATION:** 400 Street, Suite 4070  
Sacramento CA 95814

**BOARD MEMBERS**

**PRESENT** David Fong, Pharm.D., Chair  
Clarence Hiura, Pharm.D.

**STAFF**

**PRESENT:** Patricia Harris, Executive Officer  
Virginia Herold, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Judi Nurse, Supervising Inspector  
Anne Sodergren, Licensing Unit Manager  
Paul Riches, Legislative Analyst

**Call to Order**

Committee Chairman David Fong called the meeting to order at 9:00 a.m.

**Update on the Security Breach and Halt of the Administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)**

Ms. Harris reported that Business and Professions Code section 4200(a)(2)(B) requires an applicant who graduated from a foreign pharmacy school to receive a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that of domestic graduates.

To meet this requirement, the board relies on the FPGEE developed and administered by the National Association of Boards of Pharmacy (NABP).

On November 18, 2002, the NABP issued notification that it halted the examination due to a security breach. Further NABP advised that it has taken the following steps to

ensure the integrity of the examination: scores affected by the breach will be invalidated and those applicants must retake the examination, certificates that have been awarded to candidates who passed the exam affected by the compromise will be invalidated and those applicants must retake the examination, all FPGEE examinations have been cancelled until a new examination can be developed. NABP stated that it anticipates that a new examination will be developed by June 2003 and the program reinstated.

On January 29, 2003, the board received an update on the security breach. In this update were the names of 15 individuals implicated to Internet postings which may have caused or contributed to the compromise. As such the scores of those candidates were invalidated. None of the individuals listed are board licenses or have pending applications.

NABP continues to investigate all matters surrounding the breach of security and reserves the right to deny or refuse FPGEC certification should the circumstances dictate. However, NABP has informed the remaining individuals affected by the compromised exam of the status of their FPGEC certification and FPGEE score recognition.

In light of these developments, the board requested verification for 101 foreign graduate applicants on February 7, 2003, and to date has received verification for 10.

### **Update on the Sunset Review Process**

Executive Officer Harris reported that the Joint Legislative Sunset Review Committee has scheduled its next hearing for April 2, 2003. The purpose of this hearing is to consider the recommendations from the Department of Consumer Affairs. The Committee will then hold its third and last hearing about one week later to adopt its recommendations.

Committee Chair Dave Fong expressed concern to the stakeholders that it is critical that an agreement be reached to address the pharmacy manpower issue in California. The board took action on many of the recommendations that the Pharmacy Manpower Task Force proposed such as the changes to the pharmacy technician program, ratio requirements, and the ability to administer the pharmacist licensure examination more than twice a year. He added that the board agreed to the stakeholders' request that they (the stakeholders) be responsible for sponsoring legislation this year with the goal of obtaining viable solutions that could be implemented. Dr. Fong emphasized that it is especially important that the stakeholders reach consensus on these issues so that patient safety and prescription services are not impacted.

### **Competency Committee Report on the January and June 2003 California Pharmacist Licensure Examination – Open Dialogue with the Schools of Pharmacy**

Ms. Herold reported that the 675 candidates sat for the January 2003 examination that was administered in Burlingame. Examination results are scheduled for release on April 1, 2003. The June examination will be held the 17<sup>th</sup> and 18<sup>th</sup>, at the San Jose Convention Center.

Committee Chair Dave Fong stated that he has had conversations with some of the deans from the schools of pharmacy and there is concern that there is a gap between the pharmacy school curriculum and the California licensure examination. The concern is that the board may be testing candidates in subject areas that the pharmacy school has not taught. An example is that on the January examination there were questions regarding quality assurance. Although there are representatives from the schools of pharmacy on the Competency Committee to facilitate communications, Mr. Fong felt more efforts should be made in this area.

It was suggested that the Licensing Committee invite the deans or a representative from the California schools of pharmacy to the June Licensing Committee meeting to initiate this discussion. Another option is invite them to Competency Committee Retreat in August for discussion directly with the examination committee.

It was noted that the Competency Committee constructs the pharmacist licensure examination using the content outline. This outline is based on the results of a job analysis conducted by the board in 2000. The committee also uses the Competency Statement developed by the Board of Pharmacy, which outlines the level of professional competencies expected of pharmacists. Questions regarding pharmacy law are not included in the examination until the law has been in effect for at least one year.

#### **Request from Department of Health Services – Food and Drug Branch – Requesting that the Board of Pharmacy Address the Issue of Compounding vs. Manufacturing as a Joint Venture**

At the last meeting, Chair Dave Fong discussed the written request from James M. Waddell, Acting Chief for the Food and Drug Branch for the Department of Health Services. Mr. Waddell requested that due to the many recent events relative to pharmacy compounding that they would like to revisit with the board the issue of pharmacy compounding, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

The committee invited Ray Wilson from the Department of Health Services to discuss this request. Dr. Wilson stated that it is important that a joint effort to revisit this issue be initiated so that there is better understanding on how the board determines when a practice falls outside the scope of pharmacy and becomes manufacturing. He stated that his agency looks to the board for guidance as to the definition of pharmacy practice. With the many dynamic changes to pharmacy over the last years and the recent Federal guidelines, Mr. Wilson reiterated the importance of a joint effort to address this area of pharmacy practice.

The Licensing Committee agreed to establish a workgroup with the Department of Health Services and the federal Food and Drug Administration to address the issue of compounding and manufacturing. The committee agreed to begin this project upon the completion of its review of

Pharmaceutical Benefit Managers (PBMs). The project will be added as a committee strategic objective.

**Request from the Accreditation Commission on Healthcare for Approval that Pharmacies Accredited by its Organization be Exempt from Licensure pursuant to Business and Professions Code section 4127.1(d)**

Senate Bill 293 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements established by Senate Bill 293 (Section 4127.1(d) of the Business and Professions Code). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The Accreditation Commission for Health Care (ACHC) requested approval as an accreditation agency under Senate Bill 293. ACHC currently accredits both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. ACHC revisits each accredited entity every three years. Currently, 11 California pharmacies are accredited by ACHC.

The committee discussed ACHC's request and the implementation of section 4127.1(d). Stuart Venook representing ACHC provided an overview of the accreditation process. He stated that the company reviews the pharmacy's policies and procedures in advance of the site visit, they observe nurses at the home, review patient records, and they validate the pharmacy's processes through the site visit and review the complaint log. ACHC is located in North Carolina and was formed as an alternative to JCAHO, which primarily accredits hospitals. He stated that they have over 400 clients in 43 states.

The Committee advised Mr. Venook that it will refer ACHC's request to be approved as an accreditation agency to the board at its April meeting. However, they asked that the following information be provided as part of the evaluation process: the name of the 11 California pharmacies that are currently accredited, the number of pharmacies that have been denied accreditation or issued a "provisional" accreditation (and specifically any in California), the length of the accreditation process and the process for reaccreditation.

**Proposed Evaluation Criteria to Approve Accreditation Agencies Pursuant to Business and Professions Code section 4127.1(d)**

Committee Chair Dave Fong explained that Business and Professions Code section 4127.1(d) gives the Board of Pharmacy the authority to approve agencies that accredited pharmacies that compound injectable sterile products. In order to do this, the Committee requested that criteria be developed for which to evaluate the agencies. It was noted that board's approval should be based on the accreditation agency's ability to evaluate the pharmacy's conformance with

California law and good professional practice standards. The following factors were developed for board consideration when evaluating an agency: periodic inspection, documented accreditation standards, evaluation of surveyor's qualifications, acceptance by major payors, unannounced inspections of sites, board access to accreditor's report on pharmacies, length of time in operation, out-of-state abilities to accredit, length of accreditation and process for reaccreditation.

The committee recommended that the board use these proposed factors when considering an accreditation agency's request for approval pursuant to B & P Code section 4127.1(d).

### **Proposed Standards for Pharmacies that Compound Injectable Sterile Drug Products**

At its January meeting, the board agreed to move to regulation hearing the proposed amendments to CCR, title 16, section 1751 that would establish minimum standards for pharmacies that compound injectable sterile drug products. The regulation hearing is scheduled for the April board meeting. The Licensing Committee scheduled this agenda item to provide another opportunity for interested parties to comment on the proposed regulations. It was noted that the Licensing Committee was not taking oral testimony on the proposed regulation. If written comments were received, then those comments would be provided to the board; however, oral testimony had to be given during the regulation hearing on April 29, 2003.

### **Proposed Strategic Objectives for 2003/04**

Executive Officer Patricia Harris reported that last year during strategic planning, the board agreed to revise the format of its plan. With the assistance of facilitator, Lindle Hatton, the board began to revise the goal areas to better identify actual objectives and not activities. Executive staff then worked with Mr. Hatton to refine the objectives. The revised objectives were provided to the committee for its review. The committee will review the revisions and prioritize the objectives before the April board meeting and strategic planning session.

### **Adjournment**

Committee Chairman David Fong adjourned the meeting at 11:30 a.m.

# *Attachment E*

BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
<b>APPLICATIONS</b>													
<b><u>Received</u></b>													
Pharmacy	36	50	35	40	26	33	21	30	47				318
Clinics	8	13	13	7	8	9	9	4	13				84
Hospitals	3	5	4	1	2	0	8	0	6				29
Nonresident Pharmacy	3	6	8	6	3	3	5	3	5				42
Licensed Correctional Facility	0	0	0	1	0	0	0	0	0				1
Hypodermic Needles and Syringes	2	1	5	15	1	1	2	1	2				30
Out of State Distributor	11	8	10	3	6	6	8	5	5				62
Wholesalers	13	7	4	7	11	6	4	11	6				69
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0				0
Exemptees	37	53	39	53	37	40	64	66	68				457
<b><u>Issued</u></b>													
Pharmacy	48	39	35	36	29	37	33	23	33				313
Clinics	19	7	8	4	5	11	12	11	8				85
Hospital	8	0	4	2	2	0	7	2	5				30
Nonresident Pharmacy	3	7	1	4	2	5	3	10	1				36
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0				0
Hypodermic Needles and Syringes	0	1	0	5	11	1	5	0	2				25
Out of State Distributor	7	2	2	8	5	1	4	11	10				50
Wholesalers	16	6	1	10	5	4	4	2	6				54
Veterinary Food-animal Drug Retailer	1	0	0	0	0	0	0	0	0				1
Exemptees	33	33	26	37	18	18	50	37	50				302



BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
<b>Pending</b>													
Pharmacy	70	77	76	80	77	68	56	62	73				73
Clinics	30	33	34	37	40	37	34	26	24				24
Hospital	35	39	39	38	38	38	39	37	38				38
Nonresident Pharmacy	28	26	35	37	38	35	37	29	31				31
Licensed Correctional Facility	1	1	0	1	1	1	1	1	1				1
Hypodermic Needles and Syringes	3	2	7	16	5	5	1	2	1				1
Out of State Distributor	30	36	44	39	39	43	47	48	37				37
Wholesalers	33	34	37	34	39	40	39	48	44				44
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0				0
Exemptees	54	67	76	87	101	112	109	105	119				119
<b>Change of Pharmacist-in-Charge</b>													
Received	259	191	191	230	204	150	198	157	177				1757
Processed	260	120	192	181	168	226	199	186	229				1761
Pending	119	190	189	238	274	198	243	214	162				162
<b>Change of Permits</b>													
Received	49	51	48	45	19	70	28	67	28				405
Processed	95	46	46	40	34	46	20	44	38				409
Pending	163	168	170	175	160	184	192	215	205				205
<b>Discontinuance of Business</b>													
Received	27	23	14	20	15	16	21	26	16				178
Processed	16	0	1	0	29	0	33	1	32				112
Pending	49	72	85	105	*46	62	50	75	59				59

BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
<b>Renewals Received</b>													
Pharmacy/Hospitals	887	824	197	496	291	313	426	619					4053
Clinics	66	49	46	47	33	45	76	50					412
Nonresident Pharmacy	21	9	10	18	7	13	11	12					101
Hypodermic Needles and Syringes	39	15	15	19	28	26	25	11					178
Out of State Distributor	35	16	24	22	15	15	31	22					180
Wholesalers	57	28	26	37	20	36	46	31					281
Veterinary Food-Animal Drug Retailer	5	0	0	0	0	0	0	0					5
Exemptees	181	67	83	119	95	105	133	123					906

\*hand count

# *Attachment F*

**California State Board of Pharmacy**

400 R Street, Suite 4070, Sacramento, CA 95814

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GRAY DAVIS, GOVERNOR

**NO ACTION  
REPORT ONLY****COMPETENCY COMMITTEE REPORT TO THE BOARD MEMBERS  
FROM THE LICENSING COMMITTEE  
DAVID J. FONG, CHAIR  
APRIL 14, 2003****1. Report on the June 2003 Examination**

On June 17 and 18, 2003, the board will administer its June 2003 pharmacist licensure examination at the San Jose Convention and Cultural Facilities. Grading for this exam will be conducted in Sacramento on a date to be determined. Board member graders will be needed for this administration. If you are interested in assisting, please contact Debbie Anderson at (916) 445-5014, ext. 4007 to coordinate the necessary arrangements.

The application final filing date for the June 2003 examination is Friday, April 18, 2003. The board has received 986 applications for the June 2003 examination as of April 14, 2003.

**2. Report on the January 2003 Examination**

On January 14 and 15, 2003, the board administered its January 2003 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel.

The Pass/Fail letters for the January 2003 examination were mailed to the candidates on Friday, March 17, 2003. The Pass/Fail statistics for the exam, which do not include results of the regrade session to be conducted in April, are as follows (percentages for pass/fail ratios noted in parenthesis):

<b><u>EXAM ATTEMPT</u></b>	<b><u>TOTAL</u></b>	<b><u>PASSED</u></b>	<b><u>FAIL MC</u></b>	<b><u>FAIL ESSAY</u></b>
MC and Essay	675	385	86	204
(%)	(100)	(57.0)	(12.7)	(30.2)

For comparison, listed below are the Pass/Fail statistics from our January 2002 examination.

<b><u>EXAM ATTEMPT</u></b>	<b><u>TOTAL</u></b>	<b><u>PASSED</u></b>	<b><u>FAIL MC</u></b>	<b><u>FAIL ESSAY</u></b>
MC and Essay	536	269	70	197
(%)	(100)	(50.2)	(13.1)	(36.8)

Of the 385 candidates who passed the January exam, 283 have been licensed as pharmacists by the board. Approximately 11% of 385 candidates have not submitted their licensure fee and the remaining are deficient.

Attached is a January 2003 exam report that describes the performance of candidates and contains detailed demographic information about them.

**PHARMACIST LICENSURE EXAMINATION - JANUARY 2003**  
**PASS/FAIL RATES**

CANDIDATES TESTED - 675

**LOCATION OF GRADUATING SCHOOL:**

**CALIFORNIA:**

# CANDIDATES	156
% CANDIDATES	23.1%
# PASS	115
% PASS	73.7%
# FAIL	41
% FAIL	26.3%

**OTHER U.S.:**

# CANDIDATES	399
% CANDIDATES	59.1%
# PASS	228
% PASS	57.1%
# FAIL	171
% FAIL	42.9%

**FOREIGN:**

# CANDIDATES	117
% CANDIDATES	17.3%
# PASS	42
% PASS	35.9%
# FAIL	75
% FAIL	64.1%

**UNCLASSIFIED:**

# CANDIDATES	3
% CANDIDATES	0.5%
# PASS	0
% PASS	0%
# FAIL	3
% FAIL	100%

**MEAN/STANDARD DEVIATION**

		<u>ESSAY</u>	<u>M.C.</u>
CALIFORNIA	<u>MEAN</u>	71.97	217.01
	<u>S.D.</u>	7.018	18.963
OTHER U.S.	<u>MEAN</u>	68.91	206.93
	<u>S.D.</u>	8.424	25.127
FOREIGN	<u>MEAN</u>	65.77	199.03
	<u>S.D.</u>	8.304	26.681
UNCLASSIFIED	<u>MEAN</u>	69.17	171.33
	<u>S.D.</u>	8.297	7.638

**BY GENDER:**

FEMALE:

# CANDIDATES	438
% CANDIDATES	64.9%
# PASS	259
% PASS	59.1%
# FAIL	179
% FAIL	40.9%

MALE:

# CANDIDATES	237
% CANDIDATES	35.1%
# PASS	126
% PASS	53.2%
# FAIL	111
% FAIL	46.8%

MEAN/STANDARD DEVIATION

		<u>ESSAY</u>	<u>M.C.</u>
FEMALE	<u>MEAN</u>	69.49	208.53
	<u>S.D.</u>	8.193	24.541
MALE	<u>MEAN</u>	68.56	206.26
	<u>S.D.</u>	8.481	25.401

**BY DEGREE AWARDED:**

B.S.:

# CANDIDATES	255
% CANDIDATES	37.8%
# PASS	97
% PASS	38.0%
# FAIL	158
% FAIL	62.0%

PHARM.D.:

# CANDIDATES	420
% CANDIDATES	62.2%
# PASS	288
% PASS	68.6%
# FAIL	132
% FAIL	31.4%

**DEGREE AWARDED CONT:**

MEAN/STANDARD DEVIATION

		<u>ESSAY</u>	<u>M.C.</u>
B.S.	<u>MEAN</u>	66.29	199.76
	<u>S.D.</u>	8.191	27.712
Pharm.D.	<u>MEAN</u>	70.64	212.57
	<u>S.D.</u>	7.970	21.582

**BY CALIFORNIA SCHOOL - FIRST TIME CA CANDIDATES:**

UCSF:

# CANDIDATES	3
% CANDIDATES	15.0%
# PASS	2
% PASS	66.7%
# FAIL	1
% FAIL	33.3%

UOP:

# CANDIDATES	3
% CANDIDATES	15.0%
# PASS	2
% PASS	66.7%
# FAIL	1
% FAIL	33.3%

USC:

# CANDIDATES	7
% CANDIDATES	35%
# PASS	3
% PASS	42.9%
# FAIL	4
% FAIL	57.1%

Western:

# CANDIDATES	7
% CANDIDATES	35%
# PASS	3
% PASS	42.9%
# FAIL	4
% FAIL	57.1%

MEAN

ESSAY

<u>UCSF</u>	<u>UOP</u>	<u>USC</u>	<u>Western</u>
70.67	75.33	66.43	70.00

M.C.

<u>UCSF</u>	<u>UOP</u>	<u>USC</u>	<u>Western</u>
218.33	212.33	210.57	192.86

STANDARD DEVIATION

ESSAY

<u>UCSF</u>	<u>UOP</u>	<u>USC</u>	<u>Western</u>
4.509	9.609	9.519	4.243

M.C.

<u>UCSF</u>	<u>UOP</u>	<u>USC</u>	<u>Western</u>
15.948	22.502	22.441	23.681



**U.S. SCHOOLS OF PHARMACY:**

<u>SCHOOL</u>	<u># CANDIDATES</u>	
Auburn	PASS	2
	FAIL	1
Samford (Alabama)	PASS	0
	FAIL	2
University of Arizona	PASS	7
	FAIL	3
University of Arkansas	PASS	1
	FAIL	1
U.C.S.F	PASS	22
	FAIL	5
University of Pacific	PASS	34
	FAIL	7
U.S.C.	PASS	32
	FAIL	10
University of Colorado	PASS	2
	FAIL	2
University of Connecticut	PASS	2
	FAIL	0
Howard University	PASS	4
	FAIL	5
University of Florida	PASS	1
	FAIL	1
Mercer	PASS	1
	FAIL	1
U of Georgia	PASS	3
	FAIL	4
Idaho SU	PASS	3
	FAIL	1
University of Illinois (Chicago)	PASS	10
	FAIL	2

**U.S. SCHOOLS OF PHARMACY CONT:**

<u>SCHOOL</u>	<u># CANDIDATES</u>	
Butler University	PASS	1
	FAIL	0
Purdue University (Indiana)	PASS	7
	FAIL	5
Drake University (Iowa)	PASS	4
	FAIL	1
University of Iowa	PASS	3
	FAIL	0
University of Kansas	PASS	1
	FAIL	1
University of Kentucky	PASS	1
	FAIL	0
NE Louisiana University	PASS	1
	FAIL	4
Xavier	PASS	5
	FAIL	6
University of Maryland	PASS	8
	FAIL	3
Massachusetts College	PASS	22
	FAIL	21
Northeastern University (Massachusetts)	PASS	9
	FAIL	3
Ferris State University (Michigan)	PASS	2
	FAIL	6
University of Michigan	PASS	7
	FAIL	3
Wayne SU	PASS	4
	FAIL	4
University of Minnesota	PASS	7
	FAIL	3

**U.S. SCHOOLS OF PHARMACY CONT:**

<u>SCHOOL</u>	<u># CANDIDATES</u>	
University of Mississippi	PASS	1
	FAIL	0
St. Louis College of Pharmacy	PASS	4
	FAIL	6
University of Missouri-Kansas City School of Pharmacy	PASS	2
	FAIL	4
U of Montana	PASS	2
	FAIL	1
Creighton University (Nebraska)	PASS	10
	FAIL	7
U of Nebraska	PASS	6
	FAIL	0
University of New Mexico	PASS	9
	FAIL	10
Western	PASS	27
	FAIL	19
A&M Schwartz	PASS	15
	FAIL	15
St. John's University (New York)	PASS	3
	FAIL	2
Union U Albany College of Pharmacy	PASS	1
	FAIL	2
University of North Carolina	PASS	2
	FAIL	3
Ohio Northern University	PASS	1
	FAIL	2
Ohio State University	PASS	1
	FAIL	5
University of Cincinnati	PASS	1
	FAIL	0

**U.S. SCHOOLS OF PHARMACY CONT:**

<u>SCHOOL</u>	<u># CANDIDATES</u>	
University of Toledo	PASS	0
	FAIL	3
SW University of Oklahoma	PASS	0
	FAIL	1
Oregon State University	PASS	7
	FAIL	3
Duquesne	PASS	2
	FAIL	0
Philadelphia College of Pharmacy	PASS	2
	FAIL	1
Temple University	PASS	7
	FAIL	4
University of Pittsburgh	PASS	0
	FAIL	1
University of Puerto Rico	PASS	0
	FAIL	1
University of Rhode Island	PASS	2
	FAIL	0
Med University of S. Carolina	PASS	1
	FAIL	0
University of S. Carolina	PASS	2
	FAIL	0
University of Tennessee	PASS	1
	FAIL	0
University of Houston	PASS	1
	FAIL	1
University of Texas	PASS	2
	FAIL	0
University of Washington	PASS	2
	FAIL	1

**U.S. SCHOOLS OF PHARMACY CONT:**

<u>SCHOOL</u>	<u># CANDIDATES</u>	
Washington State University	PASS	0
	FAIL	2
University of Wisconsin at Madison	PASS	1
	FAIL	0
University of Wyoming	PASS	2
	FAIL	1
Nova Southeastern	PASS	4
	FAIL	0
Wilkes University	PASS	1
	FAIL	1
Bernard J Dunn	PASS	2
	FAIL	0
Midwestern AZ	PASS	10
	FAIL	9
Unclassified	PASS	0
	FAIL	3
Other/FG	PASS	42
	FAIL	75
<u>TOTAL # OF CANDIDATES</u>	PASS	385
	FAIL	290
	TOTAL	675

**YEAR OF GRADUATION:**

**1998 OR BEFORE:**

# CANDIDATES	226
% CANDIDATES	33.5%
# PASS	95
% PASS	42.0%
# FAIL	131
% FAIL	58.0%

1999 OR AFTER:

# CANDIDATES	449
% CANDIDATES	66.5%
# PASS	290
% PASS	64.6%
# FAIL	159
% FAIL	35.4%

MEAN

	<u>ESSAY</u>		<u>M.C.</u>
1998 or Before:	66.67	1998 or Before:	203.17
1999 or After:	70.29	1999 or After:	210.03

STANDARD DEVIATION

	<u>ESSAY</u>		<u>M.C.</u>
1998 or Before:	8.433	1998 or Before:	27.346
1999 or After:	7.995	1999 or After:	23.190

2001 OR BEFORE:

# CANDIDATES	353
% CANDIDATES	52.3%
# PASS	171
% PASS	48.4%
# FAIL	182
% FAIL	51.6%

2002 OR AFTER:

# CANDIDATES	322
% CANDIDATES	47.7%
# PASS	214
% PASS	66.5%
# FAIL	108
% FAIL	33.5%

MEAN

	<u>ESSAY</u>		<u>M.C.</u>
2001 or Before	67.63	2001 or Before:	203.73
2002 or After:	70.68	2002 or After:	212.12

STANDARD DEVIATION

	<u>ESSAY</u>		<u>M.C.</u>
2001 or Before:	8.308	2001 or Before:	26.400
2002 or After:	8.017	2002 or After:	22.261

**GRADUATING SCHOOL LOCATION BY COUNTRY:**

<u>COUNTRY</u>	<u># CANDIDATES</u>	
Afghanistan	PASS	0
	FAIL	2
Bulgaria	PASS	1
	FAIL	0
Canada	PASS	3
	FAIL	0
China	PASS	1
	FAIL	0
Denmark	PASS	1
	FAIL	0
Egypt	PASS	4
	FAIL	6
Ethiopia	PASS	0
	FAIL	2
Hungary	PASS	0
	FAIL	1
India	PASS	7
	FAIL	13
Iran	PASS	2
	FAIL	0

**GRADUATING SCHOOL LOCATION BY COUNTRY (continued):**

<u>COUNTRY</u>	<u>#</u>	<u>CANDIDATES</u>
Iraq	PASS	0
	FAIL	2
Italy	PASS	0
	FAIL	1
Jordan	PASS	0
	FAIL	1
Kenya	PASS	1
	FAIL	0
Korea (N&S)	PASS	2
	FAIL	1
S Korea	PASS	1
	FAIL	5
Lebanon	PASS	1
	FAIL	1
Nigeria/New Guinea	PASS	0
	FAIL	2
Peru	PASS	0
	FAIL	1
Philippines	PASS	5
	FAIL	23
Pakistan	PASS	0
	FAIL	1
Former USSR	PASS	2
	FAIL	3
Taiwan	PASS	2
	FAIL	1
U.S.A.	PASS	343
	FAIL	217
Vietnam	PASS	0
	FAIL	1



**GRADUATING SCHOOL LOCATION BY COUNTRY:**

<u>COUNTRY</u>	<u># CANDIDATES</u>	
South Africa	PASS	6
	FAIL	3
EN	PASS	0
	FAIL	1
JP	PASS	0
	FAIL	1
SK	PASS	1
	FAIL	0
UK	PASS	1
	FAIL	1
YS	PASS	1
	FAIL	0
<u>TOTAL # OF CANDIDATES</u>	PASS	385
	FAIL	290
	<u>TOTAL</u>	<u>675</u>

**PASS RATES BY US/FOREIGN:**

	<u>F</u>	<u>P</u>	<u>Rate</u>
U.S.	217	343	61.3%
Foreign	73	42	36.5%

**NUMBER OF TIMES TAKEN:**

ONE TIME:

# CANDIDATES	232
% CANDIDATES	34.4%
# PASS	113
% PASS	48.7%
# FAIL	119
% FAIL	51.3%

TWO TIMES:

# CANDIDATES	322
% CANDIDATES	47.7%
# PASS	213
% PASS	66.1%
# FAIL	109
% FAIL	33.9%

THREE TIMES:

# CANDIDATES	69
% CANDIDATES	10.2%
# PASS	35
% PASS	50.7%
# FAIL	34
% FAIL	49.3%

FOUR TIMES:

# CANDIDATES	35
% CANDIDATES	5.2%
# PASS	20
% PASS	57.1%
# FAIL	15
% FAIL	42.9%

Requalifiers

# CANDIDATES	17
% CANDIDATES	2.5%
# PASS	4
% PASS	23.5%
# FAIL	13
% FAIL	76.5%

MEAN

<u>ESSAY</u>				
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>R</u>
68.46	70.63	66.63	67.84	62.07

M.C.

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>R</u>
201.93	212.76	206.99	208.23	193.71

STANDARD DEVIATION

<u>ESSAY</u>				
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>R</u>
8.677	7.963	7.842	7.058	7.620

M.C.

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>R</u>
29.411	22.296	17.373	19.743	15.292

# *Attachment G*

# California State Board of Pharmacy Strategic Plan

## Licensing

**Goal: 2:     Ensure the professional qualifications of  
                  pharmacists and other board licensees**

**Outcome:    Licensing quality and efficiency**

<b>Objective 2.1:</b>	<b>Issue licenses within three days of a completed application:</b>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Process 100 percent of all application within 7 days of receipt.</li> <li>2. Process 100 percent of all deficiency documents within 3 days of receipt.</li> <li>3. Make a licensing decision within 3 days after all deficiencies are corrected.</li> <li>4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. <ul style="list-style-type: none"> <li>• Pharmacists</li> <li>• Intern pharmacists</li> <li>• Pharmacy technicians</li> <li>• Foreign educated pharmacists (evaluations)</li> <li>• Pharmacies</li> <li>• Non-resident pharmacies</li> <li>• Wholesaler drug facilities</li> <li>• Veterinary food animal drug retailers</li> <li>• Exemptees (the non-pharmacists who may operate sites other than pharmacies)</li> <li>• Out-of-state distributors</li> <li>• Clinics</li> <li>• Hypodermic needle and syringe distributors</li> </ul> </li> <li>5. Deny licenses to applicants not meeting board requirements.</li> </ol>
<b>Objective 2.2:</b>	<b>Implement at least 50 changes to improve licensing decisions by June 30, 2005:</b>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Review Pharmacist Intern Program.</li> <li>2. Implement changes to the Pharmacy Technician Program. <ol style="list-style-type: none"> <li>a. Use PTCB as a qualifying method for registration.</li> <li>b. Eliminate clerk-typist from pharmacist supervisory ratio.</li> <li>c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.</li> </ol> </li> </ol>

	<ol style="list-style-type: none"> <li>3. Administer a pharmacist licensure exam more than twice a year.</li> <li>4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that out side agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.</li> <li>5. Develop statutory language to grant the Board of Pharmacy the authority to grant waiver for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.</li> <li>6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.</li> <li>7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.</li> <li>8. Issue temporary permits whenever change of ownership occurs.</li> <li>9. Establish means for licensee to renew permits on line.</li> </ol>
<b>Objective 2.3:</b>	<b>Evaluate five emerging public policy initiatives affecting pharmacists care or public safety by June 30, 2005:</b>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Explore the need to regulate pharmacy benefit managers.</li> <li>2. Explore the need to regulate drugs labeled for “veterinary use only.”</li> <li>3. Explore the importation of drugs from foreign countries.</li> <li>4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.</li> </ol>
<b>Objective 2.4:</b>	<b>Cashier 100 percent of all application and renewal fees within two working days by June 30, 2005.</b>
<b>Objective 2.5:</b>	<b>Respond to 95 percent of all requests for verification of licensing information within 10 working days by June 30, 2005.</b>
<b>Objective 2.6:</b>	Update 100 percent of all information changes to licensing records within 10 days.

<b>Tasks:</b>	<ol style="list-style-type: none"><li>1. Make address and name changes.</li><li>2. Process discontinuance of businesses forms and related components.</li><li>3. Process changes in pharmacist-in-charge and exemptee-in-charge.</li><li>4. Process off-site storage applications.</li></ol>
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# *Attachment H*



# Quarterly Report

2002/03  
April 2003

## Licensing

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### Goal

Ensure the professional qualifications of pharmacists and establish the minimum standards for board-licensed facilities.

### Implementation Responsibility

Licensing Committee and Staff

Strategic Objectives		Timeline
1. Meet performance expectations for processing license applications to note deficiencies within 7 days of receipt, process deficiency documents within 3 days of receipt and issue licenses once deficiencies are corrected within 3 days.		Ongoing
10/02	Licensing data reported at October Board Meeting – average time to process provided in Sunset Report.	
11/02	Promoted from within a licensing technician to process applications for new compounding licensure program. Leaves a clerical vacancy in the facility licensure program.	
12/02	Program analyst for facility licensure program retired and until position filled, duties were reorganized.	
1/03	Licensing data reported at January Board Meeting.	
4/03	Licensing data reported at April Board Meeting.	
2. Review the Intern program.		July 2003
7/02	Board approved the sponsorship of legislation to authorize the supervision of two interns by a pharmacist.	

Strategic Objectives		Timeline
	<p><i>10/02 Review of Intern Program scheduled for March 03 committee meeting.</i></p> <p><i>3/03 Review of intern program rescheduled for future committee meeting when schools of pharmacy representatives attend and initial discussions can begin.</i></p>	
3.	Review the Technician Registration Program that will include the use of the Pharmacy Technician Certification Board (PTCB), supervision ratio of all ancillary personnel, and expanded duties that a PTCB registered pharmacy technician may perform.	July 2003
	<i>9/02 Presentation on PTCB certification process.</i>	
	<i>9/02 Recommended as a qualifier for technician registration: PTCB certification, associate degree in pharmacy technology only, eliminate "clerk typist" experience and clarify training requirements.</i>	
	<i>9/02 Recommended pharmacies to supervise 4 ancillary personnel in any combination - ancillary personnel defined as pharmacist intern, pharmacy technician and pharmacy technician trainee.</i>	
	<i>10/02 Presentation on the PTCB examination and process to Board at its public meeting.</i>	
	<i>10/02 Board approved recommended legislation and regulation changes to the technician registration program.</i>	
	<i>10/02 Board approved recommended changes to the ancillary ratio and supervision flexibility.</i>	
	<i>11/02 Responded to issues raised by the Joint Legislative Sunset Review Committee (JLSRC) regarding technician program and ratios.</i>	
	<i>11/02 Referred the board-approved pharmacy technician and ancillary ratios changes to the Legislation/Regulation Committee.</i>	
	<i>4/03 JLSRC supported board's proposal to revise registration and program requirement (SB 361).</i>	
4.	Increase the ratio on the number of clerk-typists that a pharmacist can supervise at his or her discretion.	July 2003

Strategic Objectives		Timeline
7/02	<i>Board approved regulation change to eliminate clerk-typist ratio.</i>	
8/02	<i>Proposed regulation change to eliminate clerk typist ratio pending with Legislation/Regulation Committee.</i>	
5.	Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.	July 2003
9/02	<i>Discussed proposed language. Requested interested parties to submit modifications to the proposed regulation language.</i>	
10/02	<i>Board approved proposed regulation change.</i>	
11/02	<i>Referred board-approved proposed regulation for central fill for hospital pharmacies to the Legislation/Regulation Committee.</i>	
4/03	<i>Proposed regulation awaiting notice.</i>	
6.	Explore the feasibility of offering the California pharmacist licensure examination more than twice a year.	July 2003
9/02	<i>Discussed feasibility and compared costs of offering the California exam more than twice a year.</i>	
9/02	<i>Governor signed AB 2165 which requires the Joint Legislative Sunset Review Committee to review the state's shortage of pharmacists and a course of action to alleviate the shortage including review of the licensure examination.</i>	
11/02	<i>Provided data and costs on options regarding the pharmacist licensure exam to the Joint Legislative Sunset Review Committee.</i>	
4/03	<i>JLSRC and Department of Consumer Affairs recommend that the board adopt the national exam (SB 361).</i>	
7.	Assist applicants preparing for the California pharmacists licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.	July 2003

Strategic Objectives		Timeline
<i>12/02</i>	<i>Additional practice “essay” and multiple-choice questions were added to board’s web site.</i>	
8.	Develop statutory language to grant the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.	July 2003
9.	Explore the feasibility and need to regulate Pharmacy Benefit Managers (PBMs).	July 2003
<i>12/02</i>	<i>Discussed the need to regulate PBMs and had a representative from the Department of Managed Care to provide information on their oversight responsibility.</i>	
<i>12/02</i>	<i>Recommended that the PBM discussion continue at the January Board Meeting.</i>	
<i>1/04</i>	<i>Board created an ad hoc Committee on PBM regulation comprised of 3 public board members.</i>	
<i>3/03</i>	<i>Held first Ad Hoc PBM regulation meeting.</i>	

Ongoing Objectives	
10.	Issue professional and occupational licenses to those individuals and firms that meet minimum requirements: <ul style="list-style-type: none"> <li>▪ Pharmacists</li> <li>▪ Intern pharmacists</li> <li>▪ Pharmacy technicians</li> <li>▪ Foreign educated pharmacists (evaluations)</li> <li>▪ Pharmacies</li> <li>▪ Non-resident pharmacies</li> <li>▪ Wholesaler drug facilities</li> <li>▪ Veterinary food animal drug retailers</li> <li>▪ Exemptees (the non-pharmacists who may operate sites other than pharmacies)</li> <li>▪ Out-of-state distributors</li> <li>▪ Clinics</li> <li>▪ Hypodermic needle and syringe distributors</li> </ul>
<i>9/02</i>	<i>Licensed over 415 new pharmacists within two weeks of results being released, approximately 90% issued within 24 hours of receiving fee.</i>

Ongoing Objectives	
9/02	<i>Revised intern processing requirements for foreign graduates who do not have a social security number.</i>
10/02	<i>Reported licensing data for FY 02/03 at October Board Meeting.</i>
11/02	<i>Issued 747 technician registrations in 4 weeks due to redirection of resources to process applications and decision not to respond to telephone inquiries for status of applications. Sent out over 500 letters on applications that have been deficient since July 1.</i>
12/02	<i>Reported that there was a breach of security with the FPGEE examination that resulted in the invalidation of scores. Impact was not known. FPGEE exam is suspended until a new exam is developed by June 2003.</i>
1/03	<i>Reported licensing data for FY 02/03 at January Board Meeting.</i>
1/03	<i>Board administers license exam to 675 candidates.</i>
3/03	<i>Issued 283 out of 385 pharmacist licenses from the January exam.</i>
3/03	<i>During 1<sup>st</sup> quarter of 2003, the board issued 1432 technician registrations.</i>
4/03	<i>Reported licensing data for FY 02/03 at April Board Meeting.</i>
4/03	<i>Received 912 pharmacist applications and over ½ have been processed.</i>
11. Assure that pharmacists fulfill continuing education requirements via diversity of available programs and through compliance audits.	
9/02	<i>Held informational hearing on proposed regulation to allow pharmacists to obtain CE credit from CE programs approved by other health regulatory boards.</i>
10/02	<i>Board approved granting CE to pharmacist for attending board meetings.</i>
11/02	<i>Regulation change to accept approved CE from other licensing boards noticed without a hearing and will go to the board for adoption at its January meeting.</i>
12/02	<i>Enforcement Committee recommended that 6 hours of CE be granted to pharmacists for attending board meetings.</i>
1/03	<i>Board agreed to grant 6 hours of CE to pharmacists for attending board meetings.</i>
4/03	<i>Implemented CE policy for attending April Board Meeting.</i>

## Ongoing Objectives

12. Evaluate the license application process to prevent enforcement problems and reduce application review time; implement improvements to the processing of applications consistent with protection of public health and safety; determine distribution of resources among program components.

8/02      *Reviewed accuracy of information for licensees on web site and updated information.*

9/02      *Suspended the mailing of applications due to fiscal constraints – available to download from web site.*

9/02      *Developed procedures to issue “temporary” permits to facilities during an application investigation and when there is a change of ownership.*

9/02      *Continued evaluation of workload on pharmacy technician desk – other staff redirected to assist with processing.*

11/02     *Developed procedures to address incomplete applications for changes in the PIC, DOBs and change of permits and referral to the Enforcement Unit for a citation and fine.*

12/02     *Evaluated workload on site processing desks to redistribute and prioritize assignments due to 2 vacancies in the unit.*

12/02     *Developed informational sheets for licensed facilities on what to do when changes occur to their operation.*

13. Cashier all application and renewal fees promptly.

9/02      *Redirected and trained new staff to temporarily assist with renewal cashiering.*

14. Provide accurate verification of licensure and other public record information requested regarding board licenses.

9/02      *Received 213 public records request and 1 Subpoena.*

10/02     *Web site hits were 545,474, of these, 171,814 were for web site look-up.*

12/02     *Received 225 public records request and 4 subpoenas.*

1/03      *Web site hits from Oct.- December were 530,253. Total web site hits for January 2002 – December 2002 were 1.9 million.*

3/03      *Received 200 public records requests and 1 subpoena.*

4/03      *Web site hits from Jan. – March 03 were 661,342. Total web site hits from July 1 – March 30 were 1,678,925.*

## Ongoing Objectives

15. Assure the public safety by approving waivers of licensing requirements pursuant to Business and Professions Code Sections 4118, 4137, 4197, and California Code of Regulations Section 1717.
  - 8/02 *Noticed regulation change to CCR 1717(e) to allow the delivery of medications to non-pharmacy sites when a patient is not present. Noticed without regulation hearing.*
  - 9/02 *Request from Cedars Sinai and Long Beach Medical Centers to extend technician check technician study for another two years to pursue legislation to allow the practice. Recommended that it be extended for one year only.*
  - 10/02 *Proposed regulation change to CCR 1717(e) to board for vote.*
  - 10/02 *Board adopted regulation change to CCR 1717(e).*
  - 10/02 *Request for waiver of CCR 1717(e) from Ramona Pharmacy.*
  - 10/02 *Board granted waiver of CCR 1717(e) to Romona Pharmacy pending supervising inspector review.*
  - 12/02 *Adopted amendment to CCR 1717(e) to Office of Administrative Law for approval.*
  - 3/03 *Regulation change to CCR 1717(e) became effective. Waiver is no longer necessary.*
16. Review and make recommendations to revise the Pharmacy Law and the board's regulations to reflect current practice.
  - 10/02 *Recommended changes to the pharmacy technician registration requirements and other modifications to clarify law.*
  - 10/02 *Recommended new regulation to allow automated central fill for hospital pharmacies.*
  - 10/02 *Board approved changes to the pharmacy technician program and central fill for hospital pharmacies – Referred to Legislation/Regulation Committee.*
17. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.
  - 8/02 *Held retreat to plan future examinations.*
  - 10/02 *Report from Competency Committee on the pharmacist licensure examination.*

Ongoing Objectives	
10/02	<i>Will request waiver to extend existing contract for examination consultant for one-year because of review of California examination by the Joint Legislative Sunset Review Committee.</i>
10/02	<i>Waiver to extend existing examination consultant for one year was denied. Initiated process to secure new examination consultant contract.</i>
1/03	<i>Released RFP for exam consultant.</i>
1/03	<i>Report from Competency Committee on the pharmacist licensure examination.</i>
4/03	<i>Report from Competency Committee on the pharmacist licensure examination.</i>
18.	Evaluate the distribution channels of dangerous drugs and dangerous devices from manufacturing to patients to ensure the maintenance of drug efficacy, integrity, and accountability.
7/02	<i>Met with the Veterinary Board regarding the distribution of dangerous drugs for animal use in California and via the Internet. Discussed need to clarify pharmacy law.</i>
9/02	<i>Noticed proposed regulations for pharmacies that compound sterile products – Regulation hearing scheduled for October Board Meeting.</i>
9/02	<i>DCA convened meeting with board, Medical Board and interested parties to discuss prescriber dispensing.</i>
9/02	<i>Considered proposed regulation change for central fill at hospital pharmacies.</i>
10/02	<i>Held regulation hearing to establish standards for pharmacies that compound medications. Regulations were tabled for discussion at the December Licensing Committee meeting. Will license pharmacies that compound injectable sterile drug products based on current regulations.</i>
11/02	<i>Board agreed to joint task force with Medical Board on prescriber dispensing. Enforcement Committee members will participate on task force.</i>
12/02	<i>Held a public meeting and discussed proposed regulations for pharmacies that compound injectable sterile medications.</i>
12/02	<i>Agreed to meet with the Department of Health's State Food and Drug on compounding and manufacturing issues.</i>
12/02	<i>Held second informational hearing on the standards for pharmacies that compound injectable sterile medications.</i>



Ongoing Objectives	
1/03	<i>DCA convened a meeting with Veterinary Board to discuss the distribution of dangerous drugs for animal use in CA and via the Internet. Discussed the need to clarify existing law.</i>
2/03	<i>Legislation was introduced to clarify the dispensing of dangerous drugs for animal use in CA and via the Internet to clarify and strengthen the law. Amendments were suggested and identified facility licensure for CA veterinarian school.</i>
3/03	<i>Discussed with DHS – State Food and Drug the goal of future meetings to address compounding and manufacturing. A task force will be formed upon the conclusion of the PBM ad hoc committee.</i>
4/03	<i>Scheduled hearing on proposed amendments to sterile compounding regulation.</i>